| | Application Number | 10597682 | |
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| | Filing Date | 2006-08-03 | |
| INFORMATION DISCLOSURE | First Named Inventor M | er et al. | |
| STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Art Unit | | |
| | Examiner Name | | |
| | Attorney Docket Number | MCN226USPT02 | |

| | | | | U.S. | PATENTS | |
|----------------------|------------|---------------|---------------------------|------------|---|--|
| Examiner Initial* | Cite No | Patent Number | Kind Code ¹ | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
| | 1 | 3555884 | | 1968-12-27 | Yamamoto et al. | |
| | 2 | 3672207 | | 1972-06-27 | Cramp et al. | |
| | 3 | 3762212 | | 1973-10-02 | Morley et al. | |
| | 4 | 3956923 | | 1976-05-18 | Young et al. | |
| | 5 | 4104905 | | 1978-08-08 | Zachary | |
| | 6 | 4145916 | | 1979-03-27 | Bott et al. | |
| | 7 | 4424708 | | 1984-01-10 | Meuleman | |
| | 8 | 4561289 | | 1985-12-31 | Jones | د ټر |

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

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| First Named Inventor | Maye | er et al. | | |
| Art Unit | • | | | |
| Examiner Name | | | | |
| Attorney Docket Number | | MCN226USPT02 | | |

| 9 | 4593554 | 1986-06-10 | Aarts | |
|----|---------|------------|----------------|---|
| 10 | 4643019 | 1987-02-17 | Jones | |
| 11 | 4747299 | 1988-05-31 | Fox et al. | |
| 12 | 4774830 | 1988-10-04 | Huisman | |
| 13 | 4791806 | 1988-12-20 | Wade | · |
| 14 | 4899574 | 1990-02-13 | Potteiger | |
| 15 | 4922746 | 1990-05-08 | Hulsman et al. | |
| 16 | 4991574 | 1991-02-12 | Pocknell | |
| 17 | 5042291 | 1991-08-27 | Lehmann | |
| 18 | 5149105 | 1992-09-22 | Beaver et al. | |
| 19 | 5150605 | 1992-09-29 | Simpson | · |

| Application Number | | 10597682 | |
|----------------------|------|--------------|---|
| Filing Date | | 2006-08-03 | |
| First Named Inventor | Maye | er et al. | |
| Art Unit | • | | |
| Examiner Name | | | _ |
| Attorney Docket Numb | er | MCN226USPT02 | |

| | 20 | 5156329 | 1992-10-20 | Farrell |
|---|----|---------|------------|-----------------|
| : | 21 | 5163315 | 1992-11-17 | Asai et al. |
| | 22 | 5212993 | 1993-05-25 | Mayer |
| | 23 | 5226316 | 1993-07-13 | Mally et al. |
| | 24 | 5285678 | 1994-02-15 | McDaniel et al |
| | 25 | 5333491 | 1994-08-02 | Lehmann |
| | 26 | 5345814 | 1994-09-13 | Cur et al. |
| | 27 | 5365774 | 1994-11-22 | Horiacher |
| | 28 | 5404747 | 1995-04-11 | Johnston et al. |
| | 29 | 5497654 | 1996-03-12 | Lehmann |
| | 30 | 5499529 | 1996-03-19 | Kronberg et al. |

| Application Number | | 10597682 | | |
|------------------------|------|--------------|--|--|
| Filing Date | | 2006-08-03 | | |
| First Named Inventor | Maye | er et al. | | |
| Art Unit | | | | |
| Examiner Name | | | | |
| Attorney Docket Number | | MCN226USPT02 | | |

| 31 | 5513516 | | 1996-05-07 | Stauffer |
|----|---------|----|------------|----------------|
| 32 | 5728929 | | 1998-03-17 | Gevaud |
| 33 | 5777203 | | 1998-07-07 | Stymne |
| 34 | 5831147 | | 1998-11-03 | Hoath |
| 35 | 5850036 | | 1998-12-15 | Giromini |
| 36 | 5891076 | | 1999-04-06 | Fabo |
| 37 | 5915270 | | 1999-06-22 | Lehmann |
| 38 | 5919476 | | 1999-07-06 | Fischer et al. |
| 39 | 5939619 | | 1999-08-17 | Achter et al. |
| 40 | 6050133 | | 2000-04-18 | Achter et al. |
| 41 | 6382011 | B1 | 2002-05-07 | Mayer et al. |

| Application Number | | 10597682 | | |
|---------------------------|----|--------------|--|--|
| Filing Date | | 2006-08-03 | | |
| First Named Inventor Maye | | er et al. | | |
| Art Unit | | | | |
| Examiner Name | | | | |
| Attorney Docket Numb | er | MCN226USPT02 | | |

| | 42 | 6450011 | B1 | 2002-09-17 | Mayer et al. | |
|----------------------|------------|-------------------------------|---------------------------|---------------------|---|--|
| | 43 | 6450012 | B1 | 2002-09-07 | Mayer et al. | |
| | 44 | 6460405 | B1 | 2002-10-08 | Mayer et al. | |
| | 45 | 6609414 | B2 | 2003-08-26 | Mayer et al. | |
| | 46 | 6354138 | B1 | 2002-03-12 | Ascheman et al. | |
| | 47 | 6018987 | | 2000-02-01 | Mayer et al. | |
| | 48 | 3466925 | | 1969-09-16 | Ziegehagen et al. | |
| | 49 | 3498110 | | 1970-03-03 | Burn | |
| | 50 | 3561254 | | 2002-03-12 | Argund et al. | |
| If you wisl | h to a | ı dd additional U.S. Pater | ıt citatio | n information pl | lease click the Add button. | J |
| | · | | | | CATION PUBLICATIONS | |
| Examiner Initial* | Cite No | Publication Number | Kind Code ¹ | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |

| Application Number | | 10597682 | |
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| Filing Date | | 2006-08-03 | |
| First Named Inventor | Maye | er et al. | |
| Art Unit | | | |
| Examiner Name | | | |
| Attorney Docket Number | | MCN226USPT02 | |

| | 1 | | | | | | | | | |
|-----------------------|------------|--|---|---------------|---------------------|--|--|----|--|--|
| If you wish | to ac | ld additional U.S. Publ | ished Application | citatio | n information p | lease click the Add | button. | | | |
| | | | FOREIG | GN PAT | ENT DOCUM | ENTS | | | | |
| Examiner Initial* | Cite No | Foreign Document Number³ | Country Code ² į | Kind Code4 | Publication Date | Name of Patentee Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevan Figures Appear | T5 | | |
| | 1 | 2122234 | JP | A | 1990-05-09 | Okahara | | | | |
| | 2 | 0445002 | EP | A2 | 1991-04-09 | Schvester et al. | | | | |
| | 3 | 4212938 | DE | A1 | 1993-10-21 | Schreier | | | | |
| If you wisi | h to a | ı id additional Foreign P | atent Document | citation | information p | lease click the Add | button | J | | |
| , | | | NON-PATE | NT LITE | RATURE DO | CUMENTS | | | | |
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| | 1 | | HANSON, et al., "In Quest of Sterile Packaging: Part 1, Approaches to Package Testing", Medical Device & Diagnostic Industry, August 1995, Pages 56-61. | | | | | | | |
| | 2 | | JONES, et al., "In Quest of Sterile Packaging: Part 2, Physical Package Integrity Test Methods", Medical Device & Diagnostic Industry, September 1995, Pages 81-85. | | | | | | | |
| | 3 | ARNDT, George W. Jr. 2001, Pages 1-31., Uni | | | | Bacteriological Analy | tical Manual Online, January | | | |
| If you wis | h to a | l dd additional non-pate | nt literature docu | ment ci | tation informat | tion please click the | Add button | | | |

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